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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,161	11/20/1998	YOKE MIN SIN	1459-005B	8822

22429 7590 12/11/2001  
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EXAMINER

MINNIFIELD, NITA M

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/11/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/196,161

Applicant(s)

SIN ET AL.

Examiner

Nita M. Minnifield

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 9-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Response to Amendment*

1. Applicants' amendment filed July 30, 2001 is acknowledged and has been entered. Claims 3, 5 and 8 have been amended. Claims 1-8 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains claims 9-23 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. The disclosure is objected to because of the following informalities: There are no figures/drawings in the application although the specification contains a section entitled "BRIEF DESCRIPTION OF THE DRAWING" (see p. 7, figures 1A, 1B, 1C, 2A, 2B). The transmittal letter with the originally filed application on November 11, 1998 does not indicate that any figures were submitted. The figure descriptions on p. 7 and any references to the figures should be deleted from the specification (see also pp. 8-10, 15, and 16). Appropriate correction is required.

*This objection is maintained for the reasons of record. It is noted that the specification was objected to because there are no figures (formal or informal) found in the application file, however the specification contains a "BRIEF DESCRIPTION OF THE*

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*DRAWING" (see p. 7, figures 1A, 1B, 1C, 2A, 2B). This is not a new matter rejection/objection. There are no drawings in the application file, nor is there any indication that any figure have been filed subsequent to filing date. If there are actual figures to be submitted, Applicant is free to do so in view of the fact that they were described in the originally filed application. Please note that should this application be passed to allowance, its publication will be delayed by printer queries from the Office of Publications because of the above situation; the Office of Publications will require that it be resolved before a patent is published.*

5. The amendment filed September 15, 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO: 19. The primer sequence on page 11 is 17 base pairs long, which is the same as SEQ ID NO: 17 in the RAW SEQUENCE LISTING and CRF filed November 19, 2000. The RAW SEQUENCE LISTING and CRF filed November 19, 2000 does not have a SEQ ID NO: 19; the CRF has 17 sequences. Further, Applicant is correct that p. 20 has 3 sequences but the examiner finds no "drawing originally submitted contained 9 sequence listing". With regard to the current sequence listing Applicant should indicate how sequences derived from original to show support for current SEQ ID NOs.

Applicant is required to cancel the new matter in the reply to this Office action.

*This objection is maintained for the reasons of record. It is not necessary to resubmit the sequence listings for this application in PATENTIN 3.0. The problem, as set forth above, is that the RSL and CRF contain 17 sequences; therefore there would be SEQ ID NO: 1-17. There is no SEQ ID NO: 19. Applicants should delete this amendment from the specification.*

6. Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by He et al (1997).

The claims are directed to a vaccine comprising a recombinant fusion protein, GST-iAgI, and substantially inert medium (buffer, adjuvant, immunostimulant, or carrier).

He et al disclose a recombinant fusion protein, GST-iAgI (abstract). He et al disclose that the fusion protein was expressed in *E. coli* and that "the recombinant GST-iAgI fusion protein can be used as a potential vaccine against the infection of *I. multifiliis*" (abstract). The prior art uses an adjuvant (FCA) in the vaccine composition (p. 5). The vaccine is used to protect against white spot disease in fish caused by *Ichthyophthirius multifiliis*, a ciliated protozoan parasite (p. 1). The prior art anticipates the claimed invention.

*Applicant's arguments filed July 30, 2001 have been fully considered but they are not persuasive. This rejection is maintained for the reasons of record. It is noted that Applicants have filed a Declaration under 37 CFR 1.131; however all inventors have not signed this declaration. This rejection will be maintained until a fully executed 1.131 declaration has been filed.*

7. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over He et al taken with Clark et al (1992).

He et al teach a recombinant fusion protein, GST-iAgI (abstract). He et al teach that the fusion protein was expressed in *E. coli* and that "the recombinant GST-iAgI fusion protein can be used as a potential vaccine against the infection of *I. multifiliis*" (abstract). The prior art uses an adjuvant (FCA) in the vaccine composition (p. 5). The vaccine is used to protect against white spot disease in fish caused by *Ichthyophthirius*

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*multifiliis*, a ciliated protozoan parasite (p. 1). The prior art teaches the claimed invention except for the ciliated protozoan is taxonomically related to *Ichthyophthirius multifiliis*.

However, Clark et al teach that the I-antigens of *Ichthyophthirius multifiliis* can be used in the development of protective immunity in fish (p. 6363). Clark et al teach that "...the common fish parasite *Ichthyophthirius multifiliis* (*Ich*) represents a bridge between the free-living ciliates and parasitic protozoa. As a holotrich ciliate, it is taxonomically related to both *Paramecium* and *Tetrahymena* (order Hymenostomatida) and... has I-antigens directly analogous to those found on the free living ciliates." (p. 6363, col. 2). It would have been obvious to a person of ordinary skill in the art at the time the invention was made at to use the vaccine of He et al comprising the recombinant fusion protein (GST-iAgI) and adjuvant with a reasonable expectation of protecting against infection of other taxonomically related ciliated protozoan as set forth in Clark et al. Clark et al teach that other taxonomically related ciliated protozoan have the I-antigen (immobilization antigens). The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

*Applicant's arguments filed July 30, 2001 have been fully considered but they are not persuasive. This rejection is maintained for the reasons of record. It is noted that Applicants have filed a Declaration under 37 CFR 1.131; however all inventors have not signed this declaration. This rejection will be maintained until a fully executed 1.131 declaration has been filed.*

8. No claims are allowed.

9. The information disclosure statement filed February 23, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

*It is noted that the copies of all of the cited references were not available to the Examiner. Please provide all cited references on the Form 1449 if Applicants desire to have them cited on an issued patent. References not initialed were not available to the Examiner.*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

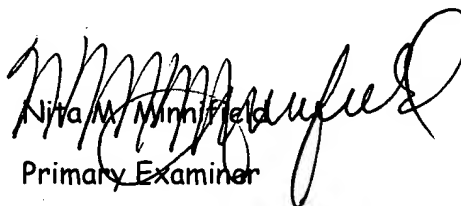
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nita M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Nita M. Winnifield  
Primary Examiner

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November 20, 2001